Clinical Outcomes of Point-of-Care Testing in the Interventional Radiology and Invasive Cardiology Setting

James H. Nichols,1* Thomas S. Kickler,1 Karen L. Dyer,1 Sandra K. Humbertson,1 Peg C. Cooper,2 William L. Maughan,3 and Denise G. Oechsle2

Background: Point-of-care testing (POCT) can provide rapid test results, but its impact on patient care is not well documented. We investigated the ability of POCT to decrease inpatient and outpatient waiting times for cardiovascular procedures.

Methods: We prospectively studied, over a 7-month period, 216 patients requiring diagnostic laboratory testing for coagulation (prothrombin time/activated partial thromboplastin time) and/or renal function (urea nitrogen, creatinine, sodium, and potassium) before elective invasive cardiac and radiologic procedures. Overall patient management and workflow were examined in the initial phase. In phase 2, we implemented POCT but utilized central laboratory results for patient management. In phase 3, therapeutic decisions were based on POCT results. The final phase, phase 4, sought to optimize workflow around the availability of POCT. Patient wait and timing of phlebotomy, availability of laboratory results, and therapeutic action were monitored. Split sampling allowed comparability of POCT and central laboratory results throughout the study.

Results: In phase 1, 44% of central laboratory results were not available before the scheduled time for procedure (n = 135). Mean waiting times (arrival to procedure) were 188 ± 54 min for patients who needed renal testing (phase 2; n = 14) and 171 ± 76 min for those needing coagulation testing (n = 24). For patients needing renal testing, POCT decreased patient wait times (phases 3 and 4 combined, 141 ± 52 min; n = 18; P = 0.02). For patients needing coagulation testing, wait times improved only when systematic changes were made in workflow (phase 4, 109 ± 41 min; n = 12; P = 0.01).

Conclusions: Although POCT has the potential to provide beneficial patient outcomes, merely moving testing from a central laboratory to the medical unit does not guarantee improved outcomes. Systematic changes in patient management may be required.

© 2000 American Association for Clinical Chemistry

Point-of-care testing (POCT) is (defined as) “laboratory testing conducted close to the site of patient care”. Its use has increased over the past decade in response to pressures for cost-containment, faster results and smaller sample volumes, and increasing acuity of inpatient populations (1–3). POCT has the potential to enhance clinical outcome (4). However, in many instances, POCT is an additional healthcare service rather than a replacement for central laboratory testing, leading to higher testing costs for reagents, operator training, and ongoing supervision (5–9). Without laboratory supervision, poor quality of POCT results and overutilization risk harming the patient and increasing costs (10–21).

Few well-controlled studies have demonstrated the clinical outcomes of POCT (22). POCT glucose has been associated with decreased length-of-stay for patients with ketoacidosis and has improved the cost of managing inpatient diabetics (23, 24). However, these studies were uncontrolled and conducted before the institution of more stringent federal regulations for testing performance (25, 26). Blood gases, electrolytes, glucose, and hemoglobin in more controlled studies were shown to decrease time spent in a postanesthesia surgical recovery unit and in the emergency room (27–30). Studies have also shown that coagulation testing is beneficial in the critically acute patient and postanesthesia recovery area for normalization of bleeding and reducing blood loss, use of blood
products, and frequency of reoperation after cardiac surgery (31, 32). However, in other studies, the use of POCT for electrolytes, blood gases, urea nitrogen, and glucose in the emergency room setting did not significantly affect length of stay or clinical outcome (33–36). The lack of effect was associated with both delays in physician acknowledgment of POCT results and failure to institute immediate therapeutic action (33) as well as a dependence of outcome on other factors in the patients’ care pathway, such as availability of diagnostic and radiologic procedures and beds (34, 35). The clinical outcome thus is a summation of multiple steps.

We examined patient delays occurring in a cardiovascular procedure setting as a performance improvement initiative. Although multiple criteria must converge before a patient is admitted for procedure, the availability of laboratory testing by the scheduled procedure time could be studied quantitatively. Through stepwise implementation of POCT, the impact of POCT on patients’ waiting times was carefully documented. To our knowledge, this is the first study examining the clinical impact of coagulation and renal function chemistry tests, particularly creatinine, in the cardiovascular procedure triage setting.

**Materials and Methods**

The Cardiovascular Diagnostic Laboratory (CVDL) performs interventional radiology, invasive cardiology, and electrophysiology procedures for the Johns Hopkins health system and referral patients from Bayview Medical Center and several outpatient clinics, e.g., arteriograms (2000/year), vascular access device insertions (1300/year), coronary angioplasties (1000/year), coronary stent placements (800/year), coronary ablations (200/year), automatic implantable cardioverter/defibrillator placements (70/year), and cardioversions (200/year). For patients arriving for elective procedures without recent laboratory results (same or previous day), physicians usually order three types of laboratory tests; prothrombin time and/or activated partial thromboplastin time; sodium, potassium, urea nitrogen, and creatinine; or a hematology panel with platelets. Because we had no means of delivering rapid platelet counts and/or platelet function studies at the point-of-care, patients requiring hematology results were excluded from the study.

In the core laboratory, prothrombin time and activated partial thromboplastin time were analyzed using citrated plasma on an MLA Electra 1600 analyzer (Medical Laboratory Automation, Pleasantville, NY), and chemistry tests were performed on serum using Roche reagents and a Roche/Hitachi 917 analyzer (Roche Diagnostics, Indianapolis, IN). Specimens were transported a distance of five floors and two buildings by courier. For POCT, whole blood analysis used the TAS analyzer (Bayer, Tarrytown, NY) for coagulation, and the Nova 16 analyzer (Nova, Waltham, MA) for renal tests. Each instrument was analytically validated by the Pathology Department before clinical use in this study. Slope offsets of −2% and 6% for potassium and urea nitrogen, respectively, were used to harmonize the Nova 16 results with the central laboratory. Sodium required a −2% slope and −3.0 mEq/L intercept adjustment, whereas creatinine did not require any offsets. All POCT samples analyzed during the study were further split to revalidate the instrument factor adjustments and ensure POCT to central laboratory comparability on an ongoing basis.

The initial phase 1 of the study (Fig. 1) investigated factors that contribute to patient delays in the preprocedure, triage area of CVDL. Delays that caused patients to miss their scheduled procedure time led to open procedure rooms, staff inefficiencies, increased costs, and patient dissatisfaction. Because the laboratory was noted as a major contributor to patient delays, management paths that involved the laboratory became the focus of this performance improvement initiative, which grew to a stepwise examination of POCT. Workflow and patient management were detailed (Fig. 2). One hundred thirty-five patients who underwent elective procedures required laboratory data and had complete timing data over a 95-day period.

In phase 2, POCT was implemented. Ten nurse-opera-
Fig. 2. CVDL patient workflow.

*, steps affected by implementation of POCT and workflow improvement initiatives. IV, intravenous drip; Coag, coagulation; Chem, chemistry; LIS, laboratory information system.
tors were trained in the operation of the TAS and Nova analyzers, and two obtained advanced training for Nova 16 maintenance. To determine the potential savings for POCT, baseline timing data were collected in this phase, including patient wait (arrival to procedure), time for sample collection (arrival to phlebotomy/sample collection), result availability (phlebotomy to laboratory result), and discharge to procedure (laboratory result to procedure). Data were examined by analyte to determine the contributions of each laboratory area (central coagulation laboratory vs central chemistry laboratory) to patient delays. During phase 2, patient management decisions continued to be made on central laboratory results while the clinical staff familiarized themselves with the operation of the POCT analyzers in their routine workflow. Thirty-eight patients were monitored during a 6-week period (n = 14 for renal and n = 24 for coagulation tests).

In phase 3, 22 patients were managed with POCT results (n = 9 for renal and n = 13 for coagulation) during 3 weeks. Timing data and patient outcomes were documented for comparison to phase 2 data. In phase 4, the final phase, the clinical staff were requested to implement any workflow and organization changes in patient management that would optimize the utilization of POCT results. Twenty-one patients were timed during a 3-week period (n = 9 for renal and n = 12 for coagulation), and split specimen, timing, and outcomes continued to be monitored. This study was conducted in accordance with the current revision of the Helsinki Declaration of 1975 and was deemed exempt from patient consent by our institutional review board.

**Results**

All CVDL patients are requested to arrive 60 min before scheduled procedure time. Those patients requiring laboratory testing are requested to arrive an additional hour or a total of 120 min before procedure. Monitoring of patient workflow in phase 1 noted that 44% of laboratory test results were not available before the scheduled procedure time. The mean patient wait was 167 ± 83 min (n = 116; median, 155 min) from arrival to procedure. This consisted of 52 ± 24 min (n = 139; range, 10–145 min) from arrival to delivery of blood to the central laboratory and 91 ± 28 min (n = 99; range, 36–165 min) from arrival to availability of laboratory results. Phase 1 did not seek to distinguish between delays attributable to renal testing or coagulation testing (i.e., distinguishing between effects of different laboratories on patient wait times).

Phase 1 outlined the flow of patients through the CVDL (Fig. 2). When a procedure is scheduled, the referring doctor is requested to order the admission tests. If the results do not arrive 24–48 h before procedure, the CVDL staff check with the referral laboratory, and, if results are still unavailable, request the patient to arrive 2 h early so that testing may be done the day of the procedure. A ward clerk registers the patient while the nurse coordinator schedules an examination room. Once the exam room opens, the patient meets with a physician to learn about the procedure, ask questions, and give consent. An examination is done, an intravenous drip is started, and samples for laboratory testing are obtained if necessary. If testing is required, the patient returns to the waiting room with an intravenous drip and waits for test results to be reviewed. Otherwise with POCT, the results are reviewed during the physician visit, the type of procedure is finalized (or canceled based on the test results), and the patient is scheduled into the next available procedure room by the floor coordinator. Because this phase implicated the core laboratories in patient delays, a formal study was constructed with the help of the Pathology Department to streamline the workflow of patients in the CVDL through the implementation of POCT.

Phase 2 studies allowed the establishment of baseline timing and patient outcome data for comparison by analyte after implementation of POCT. The results are summarized in Table 1. Overall wait times were almost 3 h (188 ± 54 min for renal and 171 ± 76 min for coagulation testing; SDs and ranges are listed in Table 1). This wait time was separated into components: for renal testing, arrival to phlebotomy, 37 min; phlebotomy to POCT, 17 min; phlebotomy to central laboratory result, 120 min; POCT result to procedure, 133 min; and central laboratory result to procedure, 41 min. Coagulation showed similar central laboratory delays: arrival to phlebotomy, 41 min; phlebotomy to POCT result, 7 min; POCT result to procedure, 123 min; central laboratory result to procedure, 65 min. With central laboratory testing, only 8% of patients who required renal testing actually met the scheduled procedure time compared with 29% of patients requiring coagulation testing. On the basis of the turnaround time differences for POCT and central laboratory results, a potential savings of 110 min for renal testing and 59 min for coagulation POCT (difference between central laboratory and POCT results excluding the transportation time) could be predicted. If the maximum savings were achieved, 92% of patients could potentially meet scheduled time (P <0.001).

These predictions were tested in phase 3, where clinical management could be based on POCT results. The data are summarized in Table 1. Despite the small sampling size, a decreasing trend in overall patient wait time was noted (not significant, n = 9 for renal and n = 13 for coagulation testing). Only the times from renal POCT result availability to procedure significantly differed from phase 2 to phase 3: 133 vs 88 min (P = 0.033).

After discussions with the CVDL managers, changes were made to improve patient flow by eliminating patient waiting times for laboratory results and improving communication between the triage nurse coordinators and procedure room floor coordinators (Fig. 2, steps indicated by *). Improved communication specifically included wireless transmitters to coordinate that patients were prepared and POCT test results were available between
# Table 1. CVDL POCT timing summary.\(^a\)

<table>
<thead>
<tr>
<th></th>
<th>Phase 2: Timing/POCT in place</th>
<th>Phase 3: Treat on POCT</th>
<th>Phase 4: Optimize POCT</th>
<th>Phases 3 and 4 combined</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean ± SD, min</td>
<td>Range, min</td>
<td>n</td>
<td>Mean ± SD, min</td>
</tr>
<tr>
<td><strong>Chemistry</strong>(^b)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Arrival–procedure</td>
<td>187.7 ± 54.4</td>
<td>100–270</td>
<td>14</td>
<td>142.0 ± 46.3</td>
</tr>
<tr>
<td>Arrival–collection</td>
<td>37.4 ± 21.0</td>
<td>10–76</td>
<td>14</td>
<td>56.9 ± 28.6</td>
</tr>
<tr>
<td>Draw–POCT</td>
<td>17.4 ± 16.5</td>
<td>0–85</td>
<td>14</td>
<td>7.0 ± 5.4</td>
</tr>
<tr>
<td>POCT–procedure</td>
<td>133.0 ± 44.8</td>
<td>60–225</td>
<td>14</td>
<td>87.6 ± 49.1</td>
</tr>
<tr>
<td>Draw–chem</td>
<td>120.1 ± 47.1</td>
<td>57–222</td>
<td>14</td>
<td>102.8 ± 48.8</td>
</tr>
<tr>
<td>Chem–procedure</td>
<td>40.5 ± 29.4</td>
<td>0–94</td>
<td>13</td>
<td>37.5 ± 29.9</td>
</tr>
<tr>
<td></td>
<td>8% met scheduled time with chem lab</td>
<td></td>
<td></td>
<td>33% met schedule with POCT</td>
</tr>
<tr>
<td><strong>Coagulation</strong>(^e)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Arrival–procedure</td>
<td>171.0 ± 76.4</td>
<td>55–360</td>
<td>22</td>
<td>150.8 ± 39.8</td>
</tr>
<tr>
<td>Arrival–collection</td>
<td>40.7 ± 25.1</td>
<td>10–85</td>
<td>22</td>
<td>40.5 ± 28.7</td>
</tr>
<tr>
<td>Draw–POCT</td>
<td>7.4 ± 6.0</td>
<td>0–20</td>
<td>24</td>
<td>7.8 ± 6.9</td>
</tr>
<tr>
<td>POCT–procedure</td>
<td>122.5 ± 65.2</td>
<td>30–280</td>
<td>24</td>
<td>103.7 ± 35.7</td>
</tr>
<tr>
<td>Draw–coag</td>
<td>66.8 ± 38.2</td>
<td>20–175</td>
<td>24</td>
<td>57.2 ± 19.7</td>
</tr>
<tr>
<td>Coag–procedure</td>
<td>64.8 ± 52.5</td>
<td>0–215</td>
<td>23</td>
<td>64.9 ± 41.9</td>
</tr>
<tr>
<td></td>
<td>29% met scheduled time with coag lab</td>
<td></td>
<td></td>
<td>23% met schedule with POCT</td>
</tr>
</tbody>
</table>

\(^a\) Timed steps in patient workflow include: arrival–procedure, total wait time; arrival–collection, wait time to phlebotomy; draw–POCT, wait time from sample collection to POCT result availability; POCT–procedure, wait time from POCT result to procedure; draw–chem or draw–coag, wait time from phlebotomy to central laboratory result availability from the core chemistry lab or the central coagulation lab, respectively; and chem–procedure and coag–procedure, wait time from central laboratory result availability from the core chemistry lab or the central coagulation lab, respectively, to procedure.

\(^b\) Chemistry analytes include sodium, potassium, creatinine, and urea nitrogen on the Nova 16 analyzer.

\(^c\) NS, not significant; chem, chemistry; coag, coagulation.

\(^d\) Bolded comparisons to phase 2 are significant at or below \(P \leq 0.05\), Student’s \(t\)-test.

\(^e\) Coagulation included prothrombin and activated partial thromboplastin on the TAS analyzer.
the triage and procedure areas of CVDL, better utilization of an existing comment section of our computerized daily scheduling program for test results, and staff re-education on the need for rapid communication and acknowledgement of results by the patient managers. Patient wait time was significantly improved for those requiring coagulation testing (phase 4): the phase 4 wait time was 109 ± 41 min compared with a phase 2 wait time of 171 ± 76 min (n = 12; P = 0.014). Additionally, the length of time between availability of coagulation POCT result and therapeutic action (procedure started) decreased from 123 ± 65 min to 64 ± 38 min (n = 12; P = 0.007). Although renal testing did not improve over phase 3 data, when the data from both phase 3 and 4 were combined (where POCT was utilized for treatment decisions), waiting times for patients requiring renal testing decreased from 188 ± 54 min to 141 ± 52 min (n = 18; P = 0.023). No difference in timing was noted between phase 3 (treating on POCT results) and phase 4 (optimizing the use of POCT results) for renal testing. Despite improvements in patient waiting times and in time between result and procedure, the percentage of patients meeting scheduled time did not improve significantly, nor were the predictions from phase 2 met (for 92% of patients achieving scheduled procedure time).

Discussion
The allure of POCT includes rapid results and the potential for quicker therapeutic action. Beneficial outcomes have not always followed, however, because delays in clinical acknowledgment of the POCT results and other components of care can negate the potential of POCT (33–36). For the triage area of our CVDL unit, multiple factors must come together before the patient is admitted to the procedure. Delays in any single step can lead to patients missing scheduled procedure times, open procedure rooms, and patient backlogs with the need for juggling other patients’ schedules, potential rescheduling of patients, and staff stress and inefficiencies.

We chose to measure the effect of laboratory testing on the final CVDL process outcome, patient wait time. Although this outcome is dependent on several factors, significant improvements in wait time were documented from the implementation of POCT. To our knowledge, this is also the first time that POCT for renal function (electrolytes, urea nitrogen, and creatinine) has been shown to impact patient outcome in this setting. We did not attempt to translate these outcomes to a cost savings because these types of extrapolations can be biased by viewpoint and by failure to include all associated costs (6).

These outcomes, however, could not have been achieved without integrating POCT into clinical management on the CVDL unit. Merely substituting POCT for central laboratory testing did not guarantee maximum efficiency and beneficial outcomes, as noted in phase 3. Systematic changes in workflow surrounding the utilization of coagulation testing in phase 4 were required to achieve the greatest improvement of patient wait times. POCT must, therefore, be integrated into the clinical management pathways to fully exploit its advantages. Because of this dependence on therapeutic practice, similar outcomes should not be predicted in other settings without consideration of how the result will be utilized in patient care. Additionally, result turnaround time comparisons between POCT and a central laboratory may predict a potential for improvement (as in phase 2), but trial implementation is required to determine whether a change is realized.

To fully exploit its advantages, POCT must harmonize with results from the central or more distant laboratory. Concerns over the quality of POCT have been widely publicized and are the motivation for federal and state regulations surrounding the performance of POCT (12, 13, 15, 16, 21, 25, 26, 37–39). A primary concern is the equivalence of POCT results obtained from nurses (40–42). Staff training, laboratory supervision, and complexity of the testing device can directly affect the quality of the final result (43). Clinical staff have primary responsibilities for patient care and may not have a full appreciation of preanalytic, analytic, and postanalytic variables (44). Simpler devices thus tend to be more successful than instruments when operated outside the central laboratory by clinical staff (43).

Our study supports these observations. We obtained POCT results that allowed the CVDL staff to triage their patients based on pathways developed previously from central laboratory testing without modification. This required initial and ongoing validation to correct the POCT biases to match the central laboratory methods. Operationally, however, the Nova and TAS were not equivalent in maintenance problems and downtime. Over the 12-week trial, we experienced problems with both analyzers in the hands of the nurse-operators that led to 29 instances of >1 h where the device was not operational. The maintenance and staff technical competency requirements as well as the low volume of patients requiring testing at this site (only 1–2 tests per day) led us to explore alternative means of delivering faster result turnaround times than performing the testing in the CVDL area.

One alternative would use the Nova 16 and TAS devices in our stat laboratory, under the supervision and performance of medical technologist staff. This site will be connected by pneumatic tube to the CVDL unit within a few months. The acquisition of a Nova 16 analyzer offers an additional advantage to other medical units of a “whole blood” creatinine and urea test at faster turnaround time than a central laboratory serum analysis.

A second, more attractive alternative would utilize existing central laboratory equipment and the new pneumatic tube system to provide “plasma” rather than “serum” creatinine and urea through the central laboratory (i.e., change from red-top serum collection tubes to green-top heparin tubes, eliminating the wait time for blood to
time beyond scheduled procedure has dropped from a surveys parallel the actual timings: the perceived wait scheduled time has improved over the past 9 months phase 2 baseline, the percentage of patients meeting their have not made significant improvements over the initial tests. We continue to monitor the percentage of patients pneumatic tube system to transport plasma samples to the tation times in the new pneumatic tube.

impacting the final outcome given comparable transpor-

(range, 36–72 min; phase 3 and 4 data), the addition of 10 prepare a patient for procedure after obtaining test results, steps, it does not incur additional costs in analyzer because of the required centrifugation and aliquoting around compared with a Nova whole-blood analyzer, manufacturers for performance of this study.

In conclusion, optimal utilization of POCT must not only consider clinical needs but also staff motivation; how the test is delivered, maintained, and supervised; and most importantly, the impact on patient outcome.

All reagents, controls, and supplies were donated by the manufacturers for performance of this study.

References


32. Despotis GJ, Santoro SA, Spitznagel E, Kater KM, Cox JL, Barnes


38. JCAHO. CAMH comprehensive accreditation manual for hospitals.

Oakbrook Terrace, IL: Joint Commission on Accreditation of Healthcare Organizations, 1998.


